

REMARKS

Prior to the entry of this Amendment, claims 1-4 and 6-13 are pending. Upon entry of this Amendment, claims 1-2 and 5 will be cancelled, claims 14-17 will be added, and claims 3-4 and 6-17 will be pending.

Claim Objections

The Office objected to claims 7 and 9 because the word "parenteral" was misspelled. This Amendment reflects the correct spelling of "parenteral."

Claim Rejections

35 U.S.C. § 103(a)

The Office rejected claims 1-4 and 6-13 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,010,702 (the '702 patent) in view of Chinese Patent Application No. 1207942 A (the '942 application), Japanese Patent Application No. 407025777 A (the '777 application), Japanese Patent Application No. 07179342 A (the '342 application), the Internet description of GERIFORTE tablets, U.S. Patent No., 5,707,631 (the '631 patent), and Japanese Patent Application No. 06056684 A (the '684 application). The Office bases its rejection on the argument that no patentable invention resides in combining ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. Without acquiescing in the rejection, Applicants cancel claims 1 and 2.

Combination of the '702 Patent with the '942 Application

Also without acquiescing in the rejection, Applicants herein amend claim 3 to an independent claim. Amended claim 3 lists Polygoni Multiflori Radix as the Principal Drug of the composition. Polygoni Multiflori Radix was not disclosed or suggested in

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the '702 patent. Its use as supplementary material in a composition used to treat dementia was disclosed in the '942 application.

The Office contends that it would have been obvious to one skilled in the art to combine the teaching of the '702 patent, which uses Applicants' *Gastrodiae Rhizoma*, *Acori Graminei Rhizoma*, *Ostericum Koreanum*, *Caulis Phyllostachyos*, *Bombycis Batryticatus*, *Fructus immaturus ponciri*, *Poria*, *Aurantii nobilis Pericarpium*, and *Glycyrrhizae Radix* with the teaching of the '942 application which uses *Polygoni Multiflori Radix* as supplemental material in a treatment for dementia.

Applicants respectfully traverse this rejection for four reasons. First, combining these references does not result in Applicants' invention. Second, it was not obvious to one of skill in the art to combine the references. Third, the effects of drug components in Oriental Medicines are not merely additive. Fourth, the use of *Polygoni Multiflori Radix* as the Principal Drug in treating dementia solves the long-standing problem of cardiovascular toxicity caused by previously known Oriental Medicine treatments for dementia, and the invention enjoys considerable commercial success.

The '702 patent teaches the use of ginseng as the Principal Drug in treating dementia. The '942 application teaches the use of celery as the Principal Drug in treating dementia. When combined, the '702 patent and the '942 application do not result in a treatment for dementia that uses *Polygoni Multiflori Radix* as the Principal Drug in treating dementia. Oriental Medicine is governed in part by the Theory of Principal, Adjuvant, Auxiliary, and Conductant Drugs, under which prescriptions are characteristically classified into four categories, the Principal Drug, or main ingredient, the adjuvant drug, the auxiliary drug, and the conductant drug. The principal drug, or

main ingredient, controls the main curative effect, the adjuvant drug supplements the curative effect, the auxiliary drug alleviates the side effects of the principal and adjuvant drugs, and the conductant drug induces the curative effects at the site of the symptom. The therapeutic effect is dominated by the Principal Drug.

It was not obvious to one skilled in the art Oriental Medicine to combine these references. In the technical field of Oriental Medicine, drugs are classified according to their functions into those with a warm or hot nature and those with a cool or cold nature. It is well-known in the art that Polygoni Multiflori Radix has a cool or cold nature. It is also well-known in the art that ginseng, the Principal Drug of the '702 application, has a hot nature, and celery, the Principal Drug of the '942 application, has a warm nature. One of skill in the art would not be directed by these references to use a drug of a cool or cold nature, such as Polygoni Multiflori Radix as the Principal Drug to treat dementia. Furthermore, one of skill in the art would have no motivation to combine the cool or cold drug Polygoni Multiflori Radix with the hot and warm drugs, ginseng and celery, respectively, to achieve a particular therapeutic effect.

The '702 patent and the '942 application teach away from using the cool or cold-natured Polygoni Multiflori Radix as a Principal Drug for treating dementia since they teach the use of warm or hot-natured Principal Drugs to treat dementia. The Oriental Medicine prescriptions of the '702 and '942 applications are not only different from, but function in a manner opposite to, the present invention. Drugs of a warm or hot nature are known in the field to be useful in treating dementia. As stated in paragraph 8 of the specification, ginseng is conventionally used in Oriental Medicine to treat dementia.

Drugs of a cool nature are not, and Applicants' invention is the first reported use of Polygoni Multiflori Radix as a Principal Drug in the treatment of dementia.

The effect of drug components in Oriental Medicine is determined by the ratios and the interactions among the components. Two prescriptions that contain the same amount of a drug can have very different effects on a particular symptom, depending on the ratios of the drug with other components of the prescription and the identity of the other components of the prescription. Therefore, the components of an Oriental Medicine prescription do not act in merely an additive manner, but rather interact in a synergistic way.

Applicants discovered that the use of Polygoni Multiflori Radix as a Principal Drug for treating dementia provided an efficacious treatment that lacks the undesirable side effects of ginseng. As stated on page 3 of the specification as filed, ginseng produces adverse cardiovascular side effects that limit its use as a dementia treatment. Applicant's invention satisfies a long-felt need in the field for an effective dementia treatment that does not cause cardiovascular side effects, which are especially problematic in the predominantly elderly target population. Additionally, Applicants' invention enjoys considerable commercial success in Korea, where the related Korean application has been allowed and issued.

Combination of the '702 Patent with the '777 Patent or the '684 Patent

For the same reasons as stated above, it was not obvious for one skilled in the art of Oriental Medicine to combine the teachings of the '702 patent with the teachings of the '777 patent. The '777 patent also uses ginseng as the Principal Drug. The English translation provided by the Office contained a mistranslation of the Japanese

word "ginseng" as "carrot." A copy of the '777 patent with the correct translation of "ginseng" is enclosed. The Principal Drug in the '342 patent is Tanjin (Salvia multioiorrhiza Bunge.) Tanjin is a type of ginseng, and is known to those skilled in the art of Oriental Medicine, and to many lay persons in Asia, to possess a hot nature.

Combination of the '702 Patent with the Geriforte Reference or the '631 Patent

For the same reasons as stated above, it was not obvious for one skilled in the art of Oriental Medicine to combine the teachings of the '702 patent with the teachings of the Geriforte reference or the '631 patent. These references utilize Chyavanprash and Trigonella foenum-graecum seed, respectively, as the Principal Drugs. The Geriforte reference teaches the use of Eugenia carophyllata and Curcuma longa as supplemental drugs in treating dementia. The '631 patent teaches the use of Saussurea costus root to treat Alzheimer's disease. However, neither of these references can be combined with the '702 patent to result in the Applicants' invention, which treats dementia with Polygoni Multiflori Radix as the Principal Drug.

For the reasons stated above, Applicants respectfully request that the rejection of claims 3-4 and 6-13 under 35 U.S.C. § 103(a) be withdrawn. Applicants respectfully submit that the claims are in condition for allowance, and in view of the foregoing amendments and remarks, respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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